



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/090,968

03/05/2002

Richard B. Streeter

VIA-17

7502

7590
Pandiscio & Pandiscio
470 Totten Pond Road
Waltham, MA 02154

03/20/2008

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

03/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|------------------------------------|--|
| Office Action Summary | Application No. 10/090,968 | Applicant(s) COHN ET AL. | |
| | Examiner Brian E. Pellegrino | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 12 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 12 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/28/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's AF submission filed on 12/3/07 has been entered.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the new limitations found in claims 1,12,14 that the apparatus comprises proximal and distal rigid sections such that the elongate body is a hollow rigid tube was not found in the written disclosure. There are many definitions for the term rigid and thus it is not clear what Applicant is intending this term to mean.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5,12,14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new limitation in claims 1,12,14 that the elongate body has rigid proximal and distal sections thus forming a rigid tube was not described in the written disclosure. The term rigid can encompass many meanings and it is not clear what Applicant meant by the term. Claims 1,12,14 recite that the elongate body is a bendable or a flexible apparatus. However, the claims also include recitations using "rigid" to describe this flexible body, but a common definition of the term is: something unbendable or non-flexible, or solid. Thus it seems contradictory as to the inclusion of the term in the claims. How can the body be considered one physical state (flexible) and then recited to encompass another (rigid or non-flexible)? The specification does not define the term "rigid" with respect to the element the Applicant is attempting to claim such that it explains whether it is some property of a material, a result of physical structure or some state of an element as compared to another element.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5,14 are rejected as best understood under 35 U.S.C. 103(a) as being unpatentable over Hojeibane (5911732) in view of Kleshinski (5755778). Hojeibane shows (Fig. 3) a bendable elongated body with at least two spring segments **5** connecting proximal and distal ends. Hojeibane also discloses that the spring segments or connectors can be elastic or of shape memory material, col. 7, lines 7,8,13,14,40. Hojeibane additionally discloses the elongate body is expandable to a second configuration, col. 5, lines 10,11. As seen in the drawing (Fig. 3) the proximal and distal end sections include solid, hollow tube sections of which the Examiner is interpreting as “rigid” as compared to the spring sections of open cell structure. It is inherent that the spring segment contracts lengthwise as it is known that spring construction sections of stents shorten or contract lengthwise, see Figs. 1A,1B,2A,2B of Palmaz (US 4733665), thus it can be said that the spring segments of Hojeibane can contract in lengthwise configuration. However, Hojeibane does not disclose that there is a plurality of barbs on fixed length sections of the proximal and distal ends to engage a vessel wall. Kleshinski teaches (Fig. 1) hollow cylindrical tube sections at the proximal and distal ends of the elongate body having barbs **20**. Kleshinski also teaches that the barbs are adapted to engage a vessel wall, col. 3, lines 41-43. It would have been obvious to one of ordinary skill in the art to incorporate barbs on all the hollow tube portions including the proximal and distal end sections as taught by Kleshinski in the stent of Hojeibane such that it enables the device to be better anchored to the vessel wall and prevents migration of the stent. The hollow solid tube sections of Hojeibane as modified by Kleshinski

including barbs can be considered rigid since they are of a solid section that does not have any separation or change in distance of material forming that section.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hojeibane '732 in view of Kleshinski '778 and Solem et al. '432. Hojeibane and Kleshinski are explained above. However, both Hojeibane and Kleshinski fail to teach the stents for use in the coronary sinus. Solem et al. disclose a method of reducing mitral regurgitation by placing a prosthesis into the coronary sinus to reduce the gap between leaflets, col. 4, lines 19-21,38,39. Solem also discloses the device is made of a shape memory alloy (col. 3, lines 38-41) which inherently enables the device to transform from a first configuration to a second configuration. It can be seen (Fig. 3) the device is a spring-like structure with barbs that extend from end to end. As in the combination above Hojeibane and Kleshinski would result in a stent with barbs. It would have been obvious to one of ordinary skill in the art to use a barbed stent of Hojeibane as modified by Kleshinski in the coronary sinus since Solem also teaches a barbed stent that is placed in the coronary sinus. The use of the hollow tube or solid proximal and distal end barbed stent would provide more structural support to the vessel walls.

Response to Arguments

Applicant's arguments filed 12/3/07 have been fully considered but they are not persuasive. Applicant argued that Hojeibane had end sections that are expandable. Additionally comments were made regarding other cited references (Palmaz and Solem) the Examiner used to support the rejections that these references did not

provide distinct end sections. However, this is a moot point since the only modification is incorporating barbs onto the stent structure of Hojeibane. Palmaz was only cited to show inherency for spring sections and Solem was only used to provide a teaching for the use of stent structure in the coronary sinus. Regarding Hojeibane, as mentioned above, the Examiner interprets the solid sections of the Hojeibane stent to be rigid since they do not have any separation or change in distance of material forming that section. The specification provides no disclosure as to what the scope of the term "rigid" is intended to encompass and thus the claims are examined as best understood and given the broadest reasonable interpretation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700

/Brian E Pellegrino/

Primary Examiner, Art Unit 3738